

SPECIALIZED CENTERS OF RESEARCH (SCORs) IN OSTEOPOROSIS, RHEUMATOID
ARTHRITIS,
AND SCLERODERMA

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RFA: AR-98-001

P.T.

National Institute of Arthritis and Musculoskeletal and Skin Diseases

For SCOR applications in Osteoporosis and Rheumatoid Arthritis

Letter of Intent Receipt Date: January 16, 1998

Application Receipt Date: March 18, 1998

For SCOR applications in Scleroderma

Letter of Intent Receipt Date: May 15, 1998

Application Receipt Date: July 15, 1998

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is reissuing a request for applications for Specialized Centers of Research (SCORs) in the following diseases: osteoporosis, rheumatoid arthritis, and scleroderma. Applicants responding to the previous RFA, AR-96-002, are especially encouraged to revise their applications and resubmit. The guidelines for this program have been revised to assist applicants with regard to content (see contact for guidelines, below). The standard PHS 398 packet gives instructions (page 15) for submitting a revised application.

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) supports Specialized Centers of Research (SCORs) in selected diseases to foster the translation of basic research to clinical application. A SCOR proposal should have a theme focused on the human disease and should include both basic research and clinical investigations that develop and generate improved strategies for current issues relating to the disease. To accomplish this, a

SCOR proposal brings together a multidisciplinary team of basic and clinical researchers to provide a mutually supportive interaction in meeting the research objectives. The individual projects must have significant merit.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Specialized Center of Research (SCOR), is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. An established clinical and research program in the disease area should be present. Foreign organizations are not eligible. International collaborations in domestic applications will only be accepted if the resources are clearly shown to be unavailable in the United States. Applications from racial/ethnic minority individuals and women and persons with disabilities are encouraged.

MECHANISM OF SUPPORT

Support of this program will be through the NIH specialized center (P50) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the PHS Grants Policy Statement.

This RFA is a one-time solicitation for these disease areas. The total requested project period for an application submitted in response to this RFA may not exceed five years. The anticipated award date is September 1998 (rheumatoid arthritis and osteoporosis) or April 1999 (scleroderma).

FUNDS AVAILABLE

The NIAMS intends to fund up to three SCORs in FY 1998 and 1999 in the scientific areas covered by this RFA. Funding is subject to the availability of resources and receipt of sufficiently meritorious applications. The estimated funds (total costs) available for the first year of support of these centers are \$3 million per year. The direct costs requested cannot exceed \$750,000 (excluding indirect costs of subcontracts) each year.

RESEARCH OBJECTIVES

The research objectives of a SCOR program are to expedite development and application of new knowledge of specific importance to diseases within the mission of the institute. A SCOR program is intended as a mechanism to focus on the human disease. To meet this objective, each SCOR application is expected to include:

1. a theme for an overall research program for a disease that addresses a critical area of opportunity to advance knowledge and patient care (documented in the program introduction and statement of objectives);
2. a multidisciplinary team of basic and clinical researchers to provide a mutually supportive interaction in meeting the research objectives (documented in the administrative core and in the program introduction and statement of objectives);
3. both basic and clinical research projects that develop innovative approaches, elaborate new and significant hypotheses, and generate improved strategies for approaching current issues relating to the disease investigated (documented in the individual projects and cores).

Clinical research is defined as patient oriented research conducted with human subjects. Research conducted on material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology, or disease may also be considered clinical research.

The individual basic and clinical research projects are expected to have high scientific merit with clear research objectives and to relate to a theme developed for that SCOR program. Ongoing NIH-funded projects may be absorbed into the SCOR if their original funding source is relinquished. Funding of a project approved in a SCOR will take precedence.

Funding may be requested for one or more core resources devoted to performing specialized support activities, such as biochemical analysis, electron microscopy, or data management. A core is defined as a resource shared by multiple investigators that should enhance research productivity and increase the functional capacity of the SCOR. Cores should be designed to provide added dimensions, generating accomplishments greater than that obtainable by the individual projects. Developmental research (for example, development of new assays or procedures) needed to further research efforts of the SCOR investigators are also appropriate for a core.

Support for large clinical trials or for applications that contain exclusively clinical or exclusively basic studies will not be provided within this program.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. Details of the interactions of the SCOR staff with the GCRC staff and research personnel may be provided in a statement describing the collaborative linkages being developed. A letter of agreement from the GCRC Program Director must be included with the application.

SPECIAL REQUIREMENTS

The director and co-director should budget for an annual one-day meeting in Bethesda, MD with NIAMS staff. The director should be prepared to devote at least 15 percent effort as the director and 20 percent effort as a project PI. Each project and core PI should be prepared to devote at least 20 percent effort.

To be funded, a SCOR must include at least three highly meritorious projects approved for five years. One of these must have the SCOR director as the principal investigator, and the highly meritorious projects must include both basic research and clinically based research.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

LETTER OF INTENT

Prospective applicants are asked to submit, by January 16, 1998 (SCOR in rheumatoid arthritis or osteoporosis) or May 15, 1997 (SCOR in scleroderma), a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NIAMS staff to estimate the potential review workload and to avoid conflict of interest in the selection of reviewers. The letter of intent is to be sent to Dr. Julia B. Freeman at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 5/95) is to be used in applying for these grants. Applications kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: ASKNIH@od.nih.gov.

Special guidelines have been developed for the SCOR program in NIAMS. These guidelines should be used in assembling the application. See INQUIRIES for obtaining a copy of these guidelines.

The RFA label available in the PHS 398 (rev. 5/95) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title, "Specialized Center of Research (SCOR) in [add disease]", and number, "AR-98-001"

must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies of the application in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, send two additional copies of the application to:

Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building, Room 5AS.25U - MSC 6500
Bethesda, MD 20892-6500
Bethesda, MD 20814 (for express/courier service)

Applications must be received by March 18, 1998 (SCOR in rheumatoid arthritis or osteoporosis) or by July 15, 1998 (SCOR in scleroderma). If an application is received after the specified date, it will be returned to the applicant without review. Individual projects from the SCOR application may be submitted to Center for Scientific Review (CSR, formerly DRG) but should document inclusion in the SCOR application under "pending support". It is understood that projects approved for funding as a component in the SCOR application will be withdrawn from review as an individual application. Amended center applications must include an introduction for each component addressing the previous critique.

REVIEW CONSIDERATIONS

Applications for SCORs will be first screened for completeness and responsiveness by NIAMS program staff with special attention to the inclusion of a multidisciplinary team and the inclusion of basic research and clinically based research projects. Incomplete applications will be returned to the applicant without further consideration. In addition, if program staff find that the application is not responsive to the RFA, it will be returned without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those application deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the National Advisory Council for NIAMS.

If the project from the SCOR director is not recommended for further consideration during the review for scientific merit, the entire SCOR application will not be reviewed further. If all the clinical research projects in a SCOR application are not recommended for further consideration, the SCOR application will not be further reviewed.

Major factors to be considered in evaluation of applications will include:

1. How the proposed SCOR combines basic and clinical research into the scientific goals and research theme;
2. If a competing continuation application, the quality and significance of the progress made in the previous funding period;
3. Scientific merit of each proposed project. [Each project will receive a priority score. The score reflects not only the feasibility of the project and adequacy of the experimental design, but also the design of the project to advance both the theme of the SCOR and the interaction between basic research and clinical investigation.]
4. Scientific merit of combining the component parts into a SCOR;
5. Technical merit and justification of each core unit;
6. Competence of the investigators to accomplish the proposed research goals, their commitment, and the time they will devote to the research program;
7. Adequacy of facilities to perform the proposed research, including laboratory and clinical facilities, instrumentation, and data management systems, when needed;

8. Adequacy of plans for interaction among investigators, and the integration of the various projects and core units;
9. Qualifications, experience and commitment of the SCOR Director and his/her ability to devote time and effort to provide effective leadership;
10. Scientific and administrative structure, including internal and external procedures for monitoring and evaluating the proposed research and for providing ongoing quality control and scientific review;
11. Institutional commitment to the program, and the appropriateness of resources and policies for the administration of a SCOR;
12. Adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

The appropriateness of the budget for the proposed program and its individual components will be considered independently of the factors indicated above.

AWARD CRITERIA

The anticipated award dates will be as early as September 1998, and as late as April 1, 1999. The primary factors determining the award will be the priority score, the overall balance of highly meritorious projects (clinical and basic research) within the application relative to the disease area, and the availability of funds. Since the NIAMS is interested in funding only the best research, individual projects or cores of lesser quality may not be funded, even if approved, under the "umbrella" of the SCOR mechanism.

INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Inquiries regarding programmatic issues and letters of intent may be directed to:

Dr. Julia B. Freeman
Centers Program

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Natcher Building, Room 5AS.19F - MSC 6500

Bethesda, MD 20892-6500

Bethesda, MD 20814 (for express/courier service)

Telephone: (301) 594-5052

FAX: (301) 480-4543

Email: freemanj@exchange.nih.gov

Copies of the guidelines for the SCOR program may be obtained from:

NIAMS Clearinghouse

1 AMS Circle

Bethesda, MD 20892-3675

Telephone: (301) 495-4484

FAX: (301) 587-4352

The guidelines are also available on the Internet at the following address:

<http://www.nih.gov/niams/grants/scorwww.htm>

Direct inquiries regarding fiscal matters to:

Sally A. Nichols

Grants Management Officer

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Natcher Building Room 5AS.49F - MSC 6500

Bethesda, MD 20892-6500

Telephone: (301) 594-3535

FAX: (301) 480-5450

Email: nicholss@exchange.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 410, 78th Congress, as amended, 42 USC 241) and administered under PHS grant policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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